CENTRAL SLEEP APNEA AND HEART FAILURE: PAP VERSUS OXYGEN VERSUS PHRENIC NERVE STIMULATION

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Northwestern University
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Saturday, January 19, 2019 – 9:20 a.m. – 9:50 a.m.

Lisa Wolfe, MD, is originally from Ohio and did her medical school training at the Ohio State University. Her residency/ fellowship training was at Northwestern University where she has been ever since. She is an associate professor of both medicine and neurology – where she is on the faculty in pulmonary / sleep and neuromuscular medicine. She is also the medical director of respiratory care at the Shirley Ryan Ability Lab (previously known as the Rehabilitation Institute of Chicago (RIC)). Dr. Wolfe's academic focus is on the use of home based ventilation and the care of those with neuromuscular diseases. She has clinical grants for this work from the Les Turner ALS Foundation and the Muscular Dystrophy Association.

CALIFORNIA THORACIC SOCIETY
A chapter of the American Thoracic Society

SATURDAY, JANUARY 19, 2019
9:20 am – 9:50 am

Central Sleep Apnea and Heart Failure: PAP versus Oxygen versus Phrenic Nerve Stimulation

Lisa F. Wolfe MD
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Overview

- Central Sleep Apnea Definitions
- Therapies
  - Acute care : PAP-ST
  - Chronic care
    - Medical therapy
    - CPAP
    - ASV
    - PAP ST
    - Phrenic Pacing
    - Oxygen

- COI - None related to this talk

Central Sleep Apnea Definitions

Types of Definition

- PSG – an event
- CMS – a medical diagnosis
- Physiology – of CSA in CHF

CSA is complicated because of the language

- To understand therapy choices you need to better understand the constructs that define central sleep apnea and in the larger sense – understand control of breathing

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Polysomnographic Central Apnea

Sleep hypoventilation is scored when the CO2 is:

- > 55 mm Hg for ≥ 10 mins.
- ↑≥ 10 (compared to awake supine) to >50 for ≥ 10 mins.

Cheyne-Stokes breathing is scored when both of the following are met:

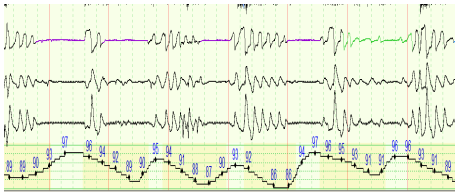
1) There are episodes of ≥ 3 central apneas / hypopneas separated by a crescendo and decrescendo change in breathing
A) a cycle length of at least 40 seconds (typically 45 to 90 seconds)

and

2) ≥ 5 central events /hr

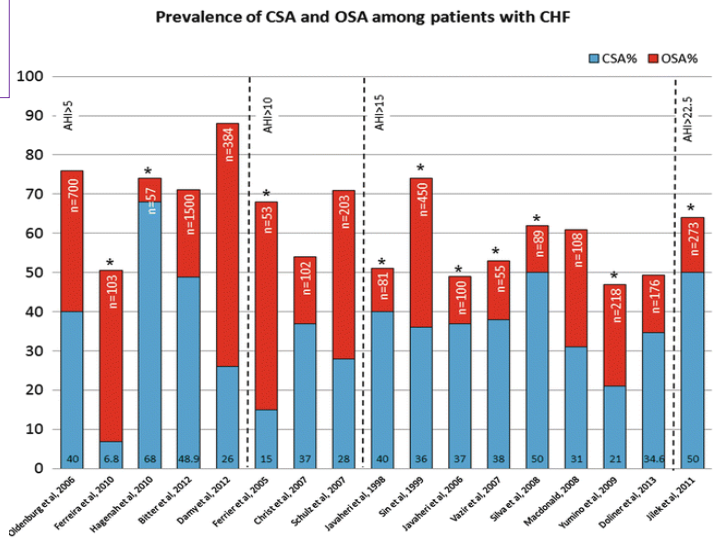
J Clin Sleep Med 2012;8(5):597-619.

Central Sleep Apnea Definitions



CSA is a marker of poor prognosis in CHF

Survival for those with HFrEF and CSA (AHI 34/h) was 45 months vs. 90 months for those without CSA (AHI <5/h, P =0.02)



1) K Terziyski;A Draganova Advances in experimental medicine and biology. , 2018, Vol.1067, p.327-351
2) Javaheri S, et al J Am Coll Cardiol 2007;49:2028–2034.

Central Sleep Apnea Definitions

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A diagnosis of central sleep apnea (CSA) requires all of the following:

1. An apnea–hypopnea index ≥ 5
2. Sum total of central apneas plus central hypopneas > 50% of the total
3. CAHI* ≥ 5 per hour

AND

4. Presence of either sleepiness, difficulty initiating or maintaining sleep, frequent awakenings, or non restorative sleep, awakening short of breath, snoring, or witnessed apneas

AND

5. No evidence of daytime or nocturnal hypoventilation

Complete facility-based attended PSG documents the following → **Diagnosis of central sleep apnea or complex sleep apnea** → Improvement of sleep-associated hypoventilation with the use of an E0470 or E0471 device on settings that will be prescribed for initial use at home (on patient's prescribed FiO2). → **(E0470) or (E0471)** Based on the treating physician's judgment

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Special Notes

- Not all types of HST are appropriate for the evaluation of CSA.
- CSA diagnosis, central apnea–central hypopnea index (CAHI) is defined as the average number of episodes of central apnea and central hypopnea per hour of sleep without the use of a PAP device.
  - 327.27/ G47.37
- For Complex Sleep Apnea/ (CECA), the CAHI is determined during the use of a PAP device after obstructive events have disappeared.
  - 327.21/ G47.31
- E0470 – Spontaneous Bi-level PAP
- E0471 – Spontaneous Timed Bi-level PAP
- Note what is not approved in this scheme:
  - CPAP
  - Oxygen

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- Age – Controversy
  - Some data has demonstrated no role for age (Bitter)
  - My experience is that older patients are at greater risk (Javaheri)
- Gender- men are at higher risk
- CO2 Gap
- Weight
- Hormonal Factors
- Autonomics
- Genetic

Bitter Sleep 2012 Sleep Breath 16(3):781–79
Javaheri S 2017 J Sleep Res 26(4):477–480

Central Sleep Apnea Definitions

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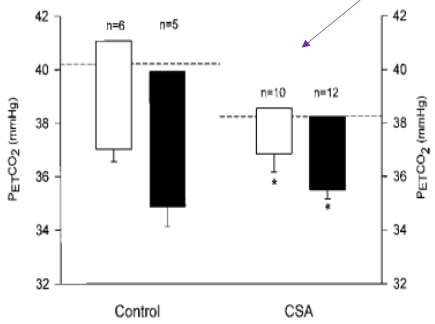
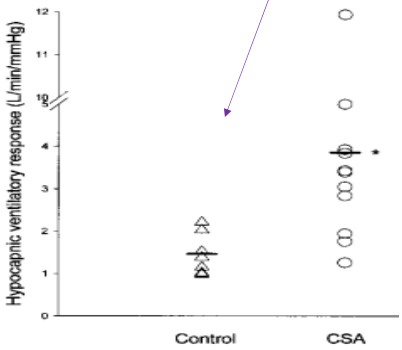
In CHF
1) Resting CO2 is to low
2) Pt's over ventilate





- Age
- Gender
- CO2 Gap
- Weight
- Hormonal Factors
- Genetic
- Autonomics

Ailiang Xie et al Am J Respir Crit Care Med Vol 165. pp 1245–1250, 2002

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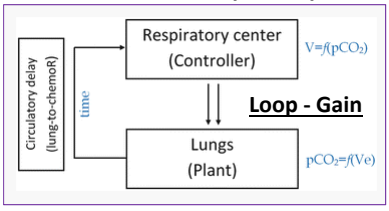

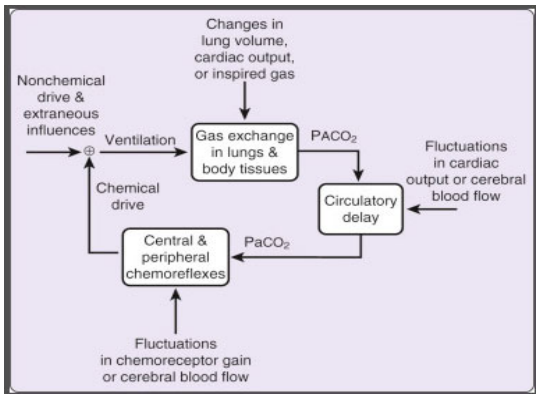

- Age
- Gender
- CO2 Gap
- Weight
- Hormonal Factors
- Genetic
- Autonomics

1) Terziyski K., Draganova A. (2018) Advances in Experimental Medicine and Biology, vol 1067.
2) Madalina Macrea, Eliot S. Katz and Atul Malhotra Principles and Practice of Sleep Medicine, Chapter 109, 1049-1058.e5

Central Sleep Apnea Definitions

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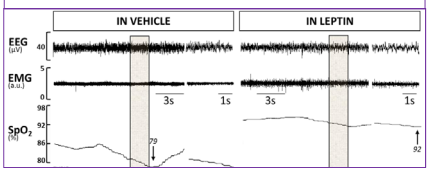
LEPTIN

1) OSA-- Leptin resistance – and associated ELEVATED Leptin levels is known to be associated with OSA
2) CSA -- in CHF patients is associated with LOW leptin levels:
   1) A cut-off value for leptin concentration < 5 ng mL has a sensitivity of 50% and specificity of 89%.
3) CHF patients had no issues with obesity

- Age
- Gender
- CO2 Gap
- Hormonal Factors/ Weight
- Genetic
- Autonomics

OSA model with intranasal leptin corrects breathing and weight



1) Olson et al – J Sleep Res. (2018) 27, 240–243
2) Berger et al AJRCCM Articles in Press. 2018

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Genetics

1) Population based genetics – in China **HSPB7 gene**

2) Specifics of genetic models with central apnea and heart disease:
   - Phox 2 B gene –
     - Associated with CCHS
       - NREM hypoventilation
       - Systole and sudden death
     - Mechanism- autonomic dysfunction
   - Mitochondrial –
     - Associated with many (PLOG/ Kearn-Sayers/ Leighs/etc):
       - central apnea separate from myopathy
       - Risk for myopathy, heart block
     - Mechanism – Failure of oxygen sensing

3) Genetic models with heart disease but NO central sleep apnea
   - Duchene Muscular Dystrophy (all dystrophin mutations)
   - Myotonic Dystrophy

- Age
- Gender
- CO2 Gap
- Hormonal Factors/ Weight
- **Genetic**
- Autonomics

1) Ramezani RJ et al *J Clin Sleep Med* 2014;10(11):1233-1239.
2) Kasi AS et al J Clin Sleep Med. 2018 Dec 15;14(12):2079-2081
3) Wang et al Int J Cardiol. 2016 Oct 15;221:926-31

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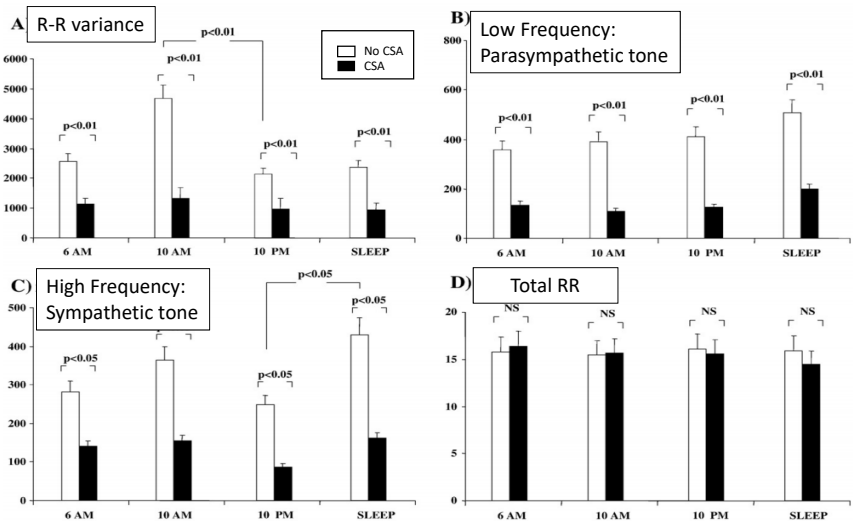

- Age
- Gender
- CO2 Gap
- Hormonal Factors/ Weight
- Genetic
- **Auto-nomics**

Ueno et al International Journal of Cardiology 148 (2011) 53–58

Central Sleep Apnea Definitions

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Atrial Fibrillation

1) The prevalence of Atrial Fibrillation is high in those with heart failure and CSA
   - OR = 4.13; 95% CI 1.53 to 11.14

2) The prevalence of Atrial Fibrillation in CSA overall is high but not as high as in those with CHF
   - OR = 1.83, 95% CI: 1.69–2.00, p < 0.0001

1) Ratz et al - SLEEPJ, 2018, 1–10
2) Bradley TD et al AJRCCM 1999;160:1101–1106.

- Age
- Gender
- CO2 Gap
- Hormonal Factors/ Weight
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- **Autonomics**

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- Which came first the chicken or the egg?

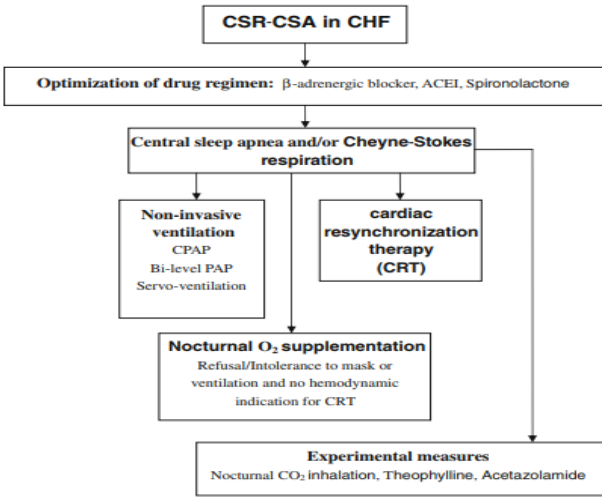
1) Ratz et al - SLEEPJ, 2018, 1–10
2) Bradley TD et al AJRCCM 1999;160:1101–1106.

- Age
- Gender
- CO2 Gap
- Hormonal Factors/ Weight
- Genetic
- **Autonomics**

Central Sleep Apnea Therapies

Therapy

- Choices should be divided in to needs for Acute Care vs Chronic Care
- First option is always to optimize CHF care
- Next option is PAP therapy
  - CPAP
  - Bi-Level
  - Servo- Ventilation
- Another option is low flow oxygen therapy
- Last option Phrenic Nerve Pacing

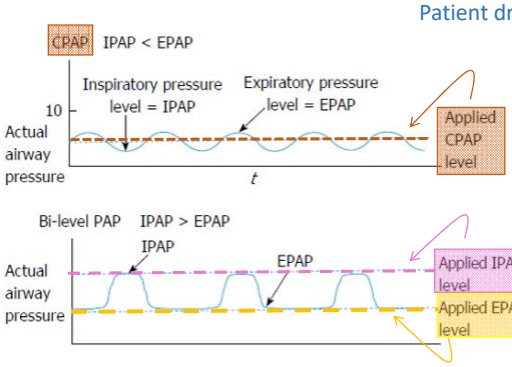


Wan et al . Sleep Breath (2013) 17:487–493

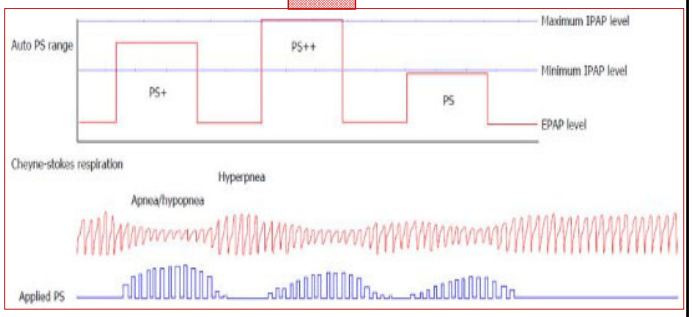
Kato et al World J Cardiol. Nov 26, 2014; 6(11): 1175-1191

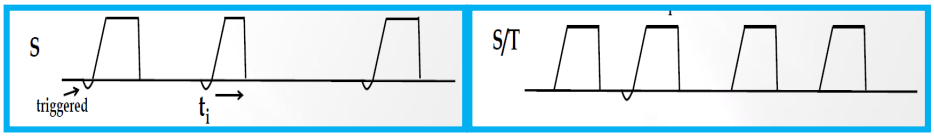
Central Sleep Apnea Therapies– The Modes

Patient driven effort to breath



ASV





Negative feedback control in which a measurement (MV - ResMed or PIF - Respironics) is compared with a target value and the difference is used to vary IPAP on a breath-by-breath basis.

Central Sleep Apnea Therapies – Acute Care

Acute Care

- The high WOB due to excess interstitial and alveoli fluid results in a risk of respiratory failure
- PAP reduces WOB but also may reduce CO
- The use of PAP therapy improves ICU outcomes in AD-CHF as compared to intubation
- There is a large variation in practice hospital to hospital which negatively impacts outcomes

CPAP vs NIV

- CPAP and NIV compared to O2 :
  - Reduce dyspnea, WOB, LOS in ICU and need for intubation.
- CPAP may be preferred
  - Cheaper
  - Easier to use
  - Can be started in the field
- NIV may be preferred in the ICU because of a better reduction in need for intubation
  - Has ben shown to reduce autonomic load
  - Endorsed as best choice by the European Society of Cardiology

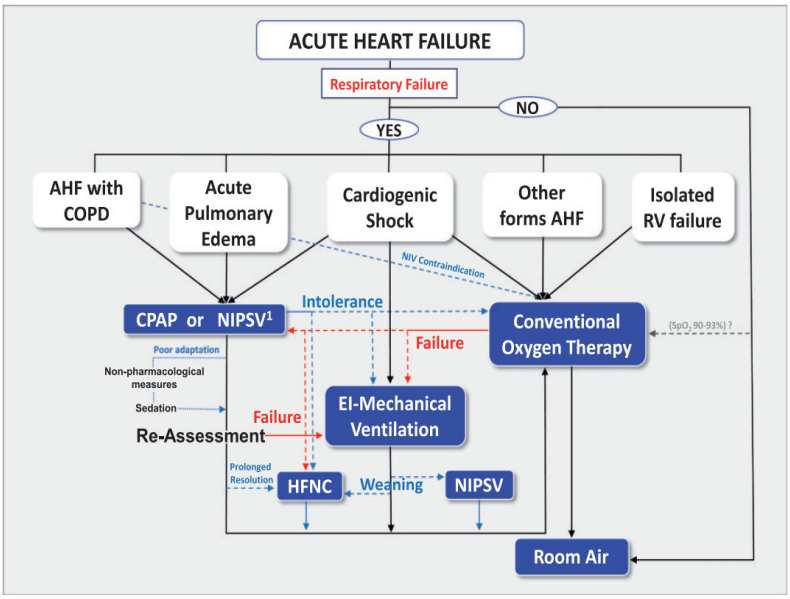
1) Tallman et al ACADEMIC EMERGENCY MEDICINE 2008; 15:355–362
2) Kulkarni et al. Circ Heart Fail. 2014 May ; 7(3): 427–433.
3) Masip et al. European Heart Journal (2018) 39, 17–25
4) Lacerda et al J. Phys. Ther. Sci. 28: 1–6, 2016

Central Sleep Apnea Therapies – Acute Care

Acute Care – Titration Recommendations

- Start with low levels of PEEP (3– 4 cmH2O) and pressure support of 7–8 cmH2O
- Increasing it progressively targeting tidal volumes are 4–7 mL/kg .
  - PS~ of 10–18 cmH2O and PEEP of 4–7 cmH2O (IPAP 14–25 cmH2O/EPAP 4–7 cmH2O)
- High pressures may cause:
  - Excessive air leakage
  - Asynchrony
  - Discomfort
  - Aerophagia/ aspiration
  - Hypotension due to falling CO

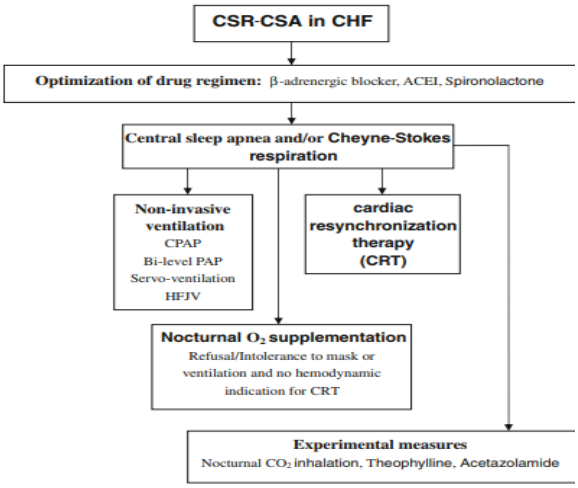
1) Tallman et al ACADEMIC EMERGENCY MEDICINE 2008; 15:355–362
2) Kulkarni et al. Circ Heart Fail. 2014 May ; 7(3): 427–433.
3) European Heart Journal (2018) 39, 17–25



Central Sleep Apnea Therapies- Chronic Care

Standard of Care for HFrEF

- ↑BNP/ PCWP/ or PAP is associated with and increase risk in CAHI
- First step is always optimizing CHF therapy
- **Afterload reduction** helps
  - Carvedilol – ↓BNP/↑LVEF
    - ↓total AHI at 6 mo (34 to 14)
    - ↓ CAI (13 to 1.9)
- **Cardiac resynchronization therapy**
  - If atrial over drive pacing improves CO/ EF – THEN the CAI ↓ (34 to 28)
  - Highly variable results
- Case reports – **Transplant and LVAD** resolves CSA
- **Positional therapy** – non supine position reduces CSA
  - Non cardiac mechanism



Wan et al . Sleep Breath (2013) 17:487–493

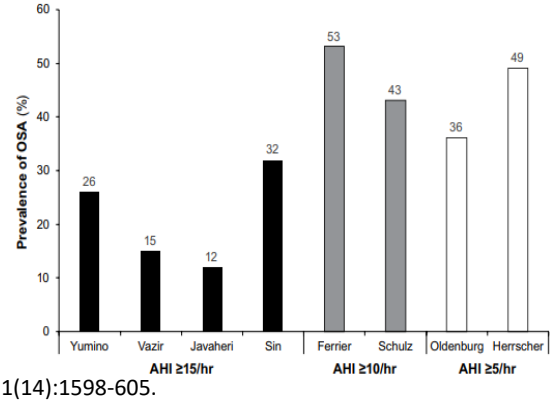
1) Tamura et al Circ J 2009; 73: 295–298
2) Vazir et al International Journal of Cardiology 2010 (138) 3, P 317-319
3) Oldenberg et al Sleep Medicine 10 (2009) 726–730
4) Luthje et al European Journal of Heart Failure (2009) 11, 273–280
5) Traversi et al Sleep Medicine Volume 34, June 2017, Pages 30-32

Central Sleep Apnea Therapies – Chronic Care

OSA

- "Wine Bottle Hypothesis"
  - Rostral fluid shifts increase obstructive events in those with HFrEF
- Obstructive events: ↑LV afterload, ↑sympathetic tone,↑BP

Prevalence of OSA in CHF



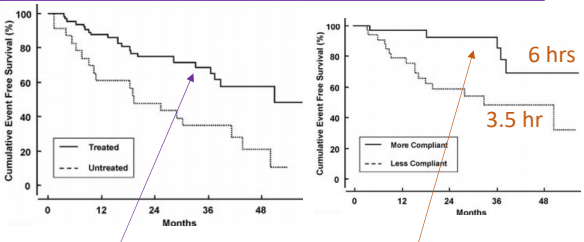
1) Yumino D, et al Circulation 2010;121(14):1598-605.
2) Khattak et al Tex Heart Inst J 2018;45(3):151-61

Central Sleep Apnea Therapies – Chronic Care

OSA

- Severe OSA (AHI >30) independently predicted 6-month cardiac hospital readmissions in patients with HFrEF. (Khayat)
- Other studies are hard because they mix OSA with CSA – But all show an increase in mortality especially for severe OSA patients with HFrEF.

CPAP – OSA and Mortality



CPAP to treat OSA reduces mortality in HFrEF

The more CPAP compliant the greater the benefit

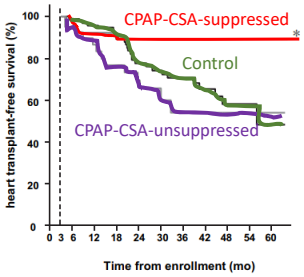
1) Khattak et al Tex Heart Inst J 2018;45(3):151-61
2) Kasai et al CHEST 2008; 133:690 – 696

Central Sleep Apnea Therapies – Chronic Care

CSA in CHF with CPAP

- Early **small** trials of CPAP in CSA with HFrEF
  - ↓AHI
  - ↓ BNP
  - ↓ plasma catecholamine
  - ↑LVEF
  - ↑trend towards improved survival

CSA in CHF with CPAP



CANPAP

1) Large trial ~100 in each grp
2) CPAP to treat CSA in HFrEF
3) When CPAP was able to resolve events the outcomes were good
4) If CSA persisted mortality was increased

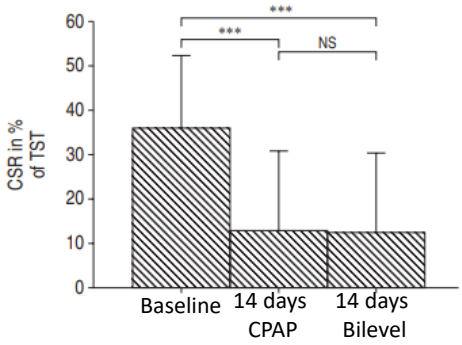
** Was the CPAP success really treating central disease?

1) Pearse et al European Journal of Heart Failure (2016) 18, 353–361
2) Artrz et al Circulation. 2007;115:3173-3180

Central Sleep Apnea Therapies – Chronic Care

Bi-level S and ST

- There is no benefit of Bi-level (S) as compared to CPAP therapy
- There is no difference in responders and non responders
- There is a theoretic concern that the Bi-Level (S) could worsen CSR by dropping CO2



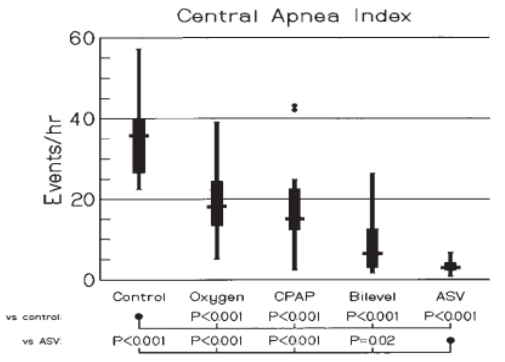
Khonlein et al Eur Respir J 2002; 20: 934–941

Central Sleep Apnea Therapies – Chronic Care

Bi-level ST

- Arousals were reduced proportionally to the reduction in CAI
- ↑SWS and REM both Bi-levelST and ASV but not with oxygen or CPAP.
- Patients preferred ASV

N=14 CHF with CSA studied on all modes on random nights



Teschler et al Am J Respir Crit Care Med Vol 164. pp 614–619, 2001

Central Sleep Apnea Therapies – Chronic Care

What went right before the trial?

- Why treat central apnea?
- Reversing the following have been shown to benefit cardiovascular out comes:
  - Hypoxia
  - Arousals
  - Increased sympathetic activity

What went right before the trial?

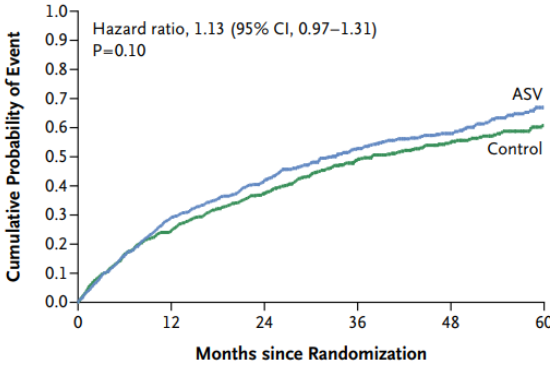
- ASV Improve hemodynamics at 6 mo:
  - ↓preload and ↓afterload
- Urinary metanephrines declined after 4 weeks on ASV
- ASV ↓ sympathetic nerve activity (SNA)
- ↑LVEF by echo after 6 months of ASV
- ↓NYHA class after 6 months of ASV
- ↑QOL (SF-36) at 3 mo of ASV vs CPAP

Brown et al Curr Opin Pulm Med 2014, 20:550–557

Central Sleep Apnea Therapies – Chronic Care

Servo Ventilation

- N= 1325
  - HFrEF (9-71%), T-AHI ≥15, C-AHI ≥ 50%
- Plan
  - RCT = Std Care vs STD Care + ASV
  - Time to first event analysis
- All-cause mortality ↑ with ASV
  - hazard ratio 1.28 P=0.01
- Cardiovascular mortality ↑ with ASV
  - hazard ratio 1.34 P=0.006



Primary End Point:

a) Death from any cause
b) Lifesaving cardiovascular intervention (transplantation, LVAD, ROSC, or shock from AICD)
c) ADHF with hospitalization

Cowie et al n engl j med 373;12

Central Sleep Apnea Therapies – Chronic Care

What went wrong?

- Was there insufficient compliance?-- NO
  - 60% of ASV grp had use ≥ 3 hr/nt
  - Re analysis for compliance (on-treatment analysis) showed no difference in out come
    - Hazard Ratio dropped from 1.37 to 1.28
- Did the device fail?– NO
  - At 12 months, the mean AHI was 6.6
  - Attempts to look statistically at AHI vs outcome made no difference in hazard risk

What went wrong?

- Did ASV negatively impact the heart? --- NO
  - No differences at up to 12 mo for:
    - Cardiac MRI
    - Echo
    - BNP– (down in both groups)
    - Inflammatory markers
      - troponin T, troponin I, sST2, galectin-3,cystatin C, creatinine, NGAL, hs-CRP and TNF-α

1) Woehrle H, et al Eur Respir J 2017; 50: 1601692
2) Cowie et al n engl j med 373;12
3) Cowie et al European Journal of Heart Failure (2018)20, 536–544

Central Sleep Apnea Therapies – Chronic Care

What went wrong?

- CSA might represent a compensatory mechanism with protective effects in HFrEF patients
- The device algorithm changed during the course of the study.
  - The addition of autoEPAP
  - Allows PS = 0
  - Reduction in rate of increase ↑in PS
  - Rapid ↓ PS when pressure support requirements remain stable

What went wrong?

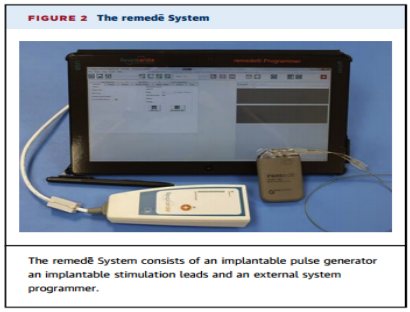
- Alkalosis due to over ventilation may have increased risk of arrhythmia.
- Although the mean AHI and O2 stats were normal there were outliers.

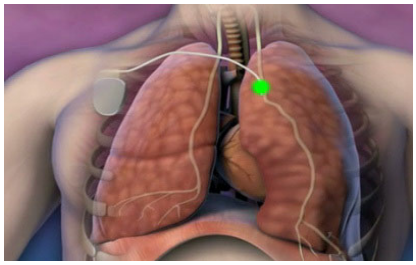
1) Khayat et al CHEST 2016; 149(4):900-904

Pacing and Central Apnea

- Unilateral, transvenous phrenic nerve stimulation
- In CSA associated CHF the stimulation results in:
  - a more regular breathing pattern
  - fewer apneic events
  - improved oxygen saturation
  - increased end-tidal carbon dioxide
    - without suppressing the intrinsic drive to breathe

William T. Abraham
J Am Coll Cardiol HF
2015;3:360–9

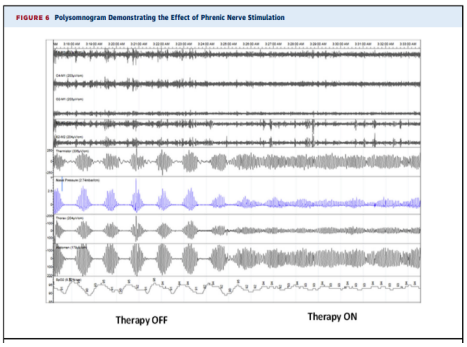




Pacing and Central Apnea

6 month prospective trial

- N=57
- 55% reduction in apnea-hypopnea index from baseline to 3 months
  - But AHI remained in the abnormal range (44.9 to 22.4)
    - Persistent events are obstructive
- Improved
  - Sleep quality
  - Daytime sleepiness
  - Oxygenation
- Serious adverse events occurred in 26%
- Results unchanged at 6 months



William T. Abraham
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Maria Rosa Costanzo,Lancet 2016; 388: 974–82

Pacing and Central Apnea

Remedé System Pivotal Trial Group

- Prospective RCT
  - N= ~75 in each grp
    - 31 sites(Europe & US)
  - PSG baseline and 6 mo
    - Baseline ave. AHI 46
    - Baseline ave. CAHI 28
  - 64% with HFrEF
  - 40% with Afib
- Primary outcome
  - ≥50% reduction in AHI

Remedé System Pivotal Trial Outcomes

- At 6 mo Paced pt's statistically significant improvements
  - AHI 26
  - CAHI 6
  - ESS = - 3.6
  - Global Assessment = 55% improvement

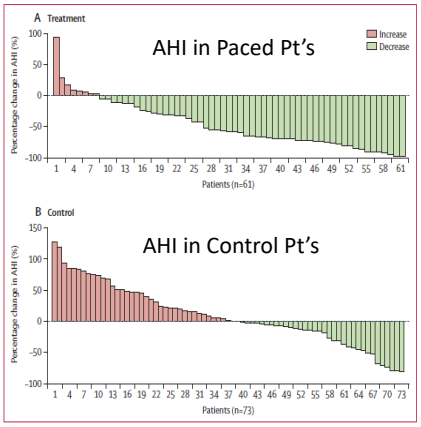
"Specifically in reference to your overall health, how do you feel today as compared to how you felt before having your device implanted?"

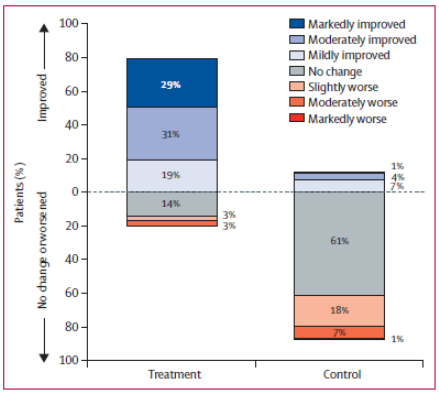
1. Markedly worse
2. Moderately worse
3. Slightly worse
4. No change
5. Mildly improved
6. Moderately improved
7. Markedly improved

Maria Rosa Costanzo,Lancet 2016; 388: 974–82

Pacing and Central Apnea

Remedé System Pivotal Trial Outcomes

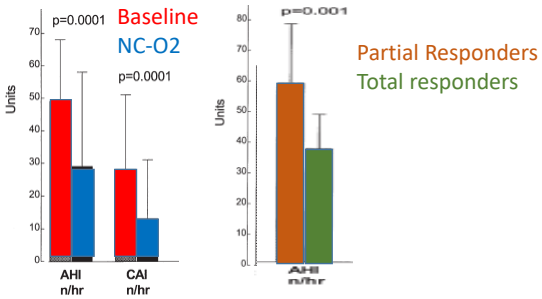




Central Sleep Apnea Therapies – Oxygen Therapy

Classic study of O2 for HCSR

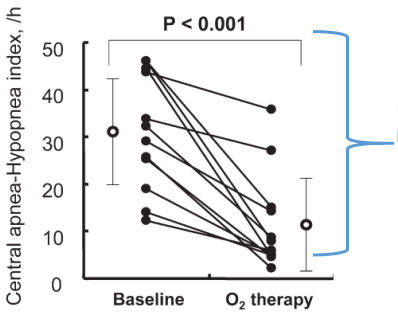
- O2 response was variable
- The hypothesis was that severity of disease would predict response
- That was not the case



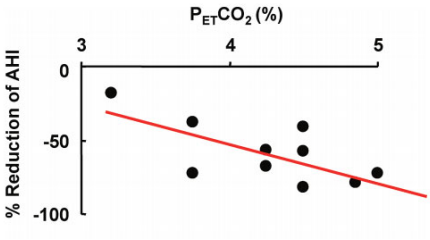
1) Koichiro Sugimura et al Tohoku J. Exp. Med., 2016, 239, 39-45
2) Javaheri et al SLEEP, Vol. 22, No. 8, 1999

Central Sleep Apnea Therapies – Oxygen Therapy

- Given the hyperpnea mechanism of CSR a mechanism to increase CO2 may buffer the process
- Oxygen therapy has been shown to effectively reduce central sleep apnea
  - But there is a variable response
  - Base line CO2 inversely predicts response to oxygen therapy



There are responders and non responders to low flow O2 therapy



Inverse relationship between CO2 and response to NC-O2. The cut off for a 50% response is 32

1) Koichiro Sugimura et al Tohoku J. Exp. Med., 2016, 239, 39-45
2) Javaheri et al SLEEP, Vol. 22, No. 8, 1999

Central Sleep Apnea Therapies – Oxygen Therapy

Table 3. Multivariate regression analysis for the variables contributed to the variance of %ΔAHI.

Factors	Regression coefficient	P value
Age	0	0.63
BNP	0	0.76
$P_{ET}CO_2$	−26.3	0.004
AHI	0	0.91
Ventilatory response to CO_2	0	0.74
Circulation time	0	0.89

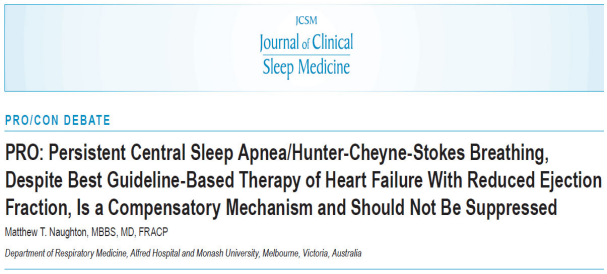
- Control of heart failure does not explain the response to NC-O2

Koichiro Sugimura et al Tohoku J. Exp. Med., 2016, 239, 39-45

Should we be treating this anyway?

"Oxygen is a toxic gas"
MT Naughton ATS 2018

- **IF** CSA-HCSB continues despite the "optimal therapy,"
  - **THEN** CSA-HCSB itself, is a compensatory mechanism to offset the adverse effects of HF
- CSA-HCSB offset the known adverse effects of HF
  - edematous lungs with restricted lung volumes
  - exhaustion due to an increased WOB
- The dyspnea of HF is akin to walking up a steep hill, and CSA-HCSB is akin to stopping periodically to "catch your breath."
- Efficiency of breathing (pressure time product) in CSA-HCSB is improved
- CSA-HCSB can assist forward cardiac output.
  - The adrenaline surge augments stroke volume


JCSM
Journal of Clinical Sleep Medicine

PRO/CON DEBATE

PRO: Persistent Central Sleep Apnea/Hunter-Cheyne-Stokes Breathing, Despite Best Guideline-Based Therapy of Heart Failure With Reduced Ejection Fraction, Is a Compensatory Mechanism and Should Not Be Suppressed

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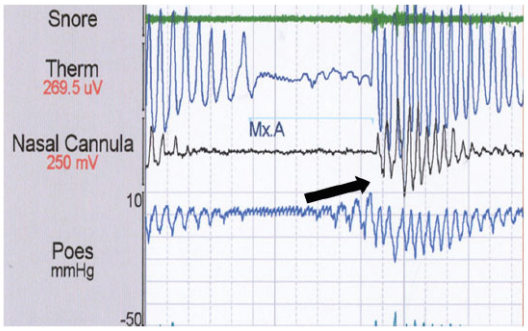
Journal of Clinical Sleep Medicine, Vol. 14, No. 6 June 15, 2018

Should we be treating this anyway?

- The unique characteristics of CSA-HCSB:
  - provide a natural compensatory mechanism to offset the adverse effects of HF
  - May be most similar to CPAP (see figure)

Glottic closure at the end of a CSA event my help to stent airways open



Journal of Clinical Sleep Medicine, Vol. 14, No. 6 June 15, 2018

Summary

- Optimizing HF treatment is agreed upon as effective therapy
- CPAP therapy to treat OSA in HFrEF makes good sense
- PAP therapy to reduce CSA does not have a role in HFrEF
- As for Oxygen we will await the NIH trial
- As for Pacing – a role can not be clearly developed until we understand if there is a benefit to treating central apnea

Thank-You

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